CLAIMS

1. Use of a pharmacologically active agent in the manufacture of a particulate medicament also comprising a hydrogel, for use in the treatment of a subject by particle injection.

2. Use according to claim 1, wherein the mean mass aerodynamic diameter of the particles is from 10 to 100 μm.

3. Use according to claim 1 or 2, wherein the envelope density of the particles is from 0.8 to 1.5 g/cm^3.

4. Use according to any one of the preceding claims, wherein the pharmacologically active agent is a gene construct.

5. Use according to claim 4, wherein the gene construct comprises a sequence coding for an antigen operably linked to a promoter.

6. Use according to any one of the preceding claims, wherein the hydrogel is agarose or dextran.

7. Use according to claim 6, wherein the hydrogel is agarose and the particles of the medicament further comprise dextran as an excipient.

8. Use of an expressible gene construct encoding an antigen in the manufacture of a particulate medicament comprising a hydrogel loaded with the said construct, for use as a nucleic acid vaccine for delivery to a subject by particle injection.

9. Use of an antigen in the manufacture of a particulate medicament for use as a vaccine for delivery to a subject by particle injection.

10. A method for making a powdered pharmaceutical composition suitable for administration by particle injection, said method comprising:

(a) contacting hydrogel particles with an aqueous composition containing a pharmacologically active agent, thereby to load the particles with the agent;

(b) optionally, separating the thus loaded hydrogel particles from the aqueous composition in an at least partial drying step and contacting the separated

particles with an aqueous composition containing said pharmacologically active agent, thereby to load further the particles with the agent;

(c) if step (b) has been carried out, optionally repeating said step one or more times;

(d) separating the thus loaded hydrogel particles from the aqueous composition in a drying step; and

(e) obtaining the desired powdered pharmaceutical composition suitable for use in a transdermal powder injection device.

11. A method for making a powdered pharmaceutical composition, said method comprising:

(a) providing a mixture of pre-formed hydrogel particles;

(b) contacting the hydrogel particles with an aqueous composition containing a pharmacologically active agent for a period sufficient to allow the agent to associate with the hydrogel particles and be incorporated therewith; and

(c) separating the hydrogel particles from the aqueous composition in a drying step to obtain a powdered pharmaceutical composition, wherein said composition comprises said hydrogel particles having the active agent incorporated therewith, and further wherein said composition is suitable for use in a transdermal powder injection device.

12. A method for making a powdered pharmaceutical composition, said method comprising:

(a) providing a mixture of pre-formed hydrogel particles;

(b) suspending the hydrogel particles in an aqueous composition containing a pharmacologically active agent for a period sufficient to cause the particles to swell and incorporate the active agent therein; and

(c) removing water and other solvents from the suspension in a drying step to obtain a powdered pharmaceutical composition comprising the hydrogel particles that have the active agent incorporated therewith, wherein the mass mean

aerodynamic diameter of the hydrogel particles in said powder composition is 10 to 100 μm.

13. A method for making a powdered pharmaceutical composition, said method comprising:

(a) providing a mixture of pre-formed hydrogel particles;

(b) contacting the hydrogel particles with an aqueous composition containing a pharmacologically active agent for a period sufficient to allow the agent to associate with the hydrogel particles and be incorporated therewith;

(c) separating the hydrogel particles from the aqueous composition in at least a partial drying step to obtain primary loaded hydrogel particles having the active agent incorporated therewith;

(d) contacting the primary loaded hydrogel particles with an aqueous composition containing said pharmacologically active agent for a period sufficient to allow further agent to associate with the hydrogel particles and be incorporated therewith;

(e) separating the hydrogel particles formed in step (d) from the aqueous composition in at least a partial drying step to obtain secondary loaded hydrogel particles having the active agent incorporated therewith; and

(f) drying the secondary loaded hydrogel particles to obtain a powdered pharmaceutical composition.

14. The method of claim 13, wherein prior to step (f), the secondary loaded hydrogel particles formed in step (e) are contacted at least one further time with an aqueous composition containing said pharmacologically active agent for a period sufficient to allow still further agent to associate with the hydrogel particles and be incorporated therewith.

15. The method of any one of claims 10 to 14, wherein the hydrogel particles in step (b) are contacted with the aqueous composition while in a dry state.

16. The method of any one of claims 10 to 14, wherein the hydrogel particles in step (b) are contacted with the aqueous composition while in a wet, pre-hydrated state.

17. The method of any one of claims 10 to 16, wherein the hydrogel particles are selected from the group consisting of agarose, dextran, polyethylene glycol and polybutyleneterephthalate particles.

18. The method of any one of claims 10 to 17, wherein the active agent is present in the powdered pharmaceutical composition in an amount ranging from about 0.1 to 85 wt% of the composition.

19. The method of any one of claims 10 to 18, wherein the powdered pharmaceutical composition is formed using a freeze-drying step.

20. The method of any one of claims 10 to 18, wherein the powdered pharmaceutical composition is formed using a spray-drying step.

21. A pharmaceutical composition comprising a hydrogel and a pharmacologically-active agent, wherein the composition is a powder suitable for transdermal or transmucosal delivery to a subject by high velocity powder injection.

22. A pharmaceutical composition comprising solid particles of about 10 to 100 μm in diameter where each particle comprises a hydrogel having incorporated therewith a pharmacologically active agent, the particles being suitable for transdermal or transmucosal delivery to a subject by high velocity powder injection.

23. The composition of claim 21 or 22, wherein the hydrogel is agarose.

24. The composition of any one of claims 21 to 23, wherein the active agent is a peptide.

25. The composition of any one of claims 21 to 24 in combination with written labeling instructions for administration of the particles by transdermal or transmucosal, high-velocity, powder injection.

26. A unit dosage form of the composition of any one of claims 21 to 24.

27. An article of manufacture for the transdermal or transmucosal delivery of a pharmacologically-active agent to a subject, which article comprises a pharmaceutical composition of any one of claims 21 to 24 in a container containing a unit dose of active agent.

28. The article of manufacture of claim 27, wherein the hydrogel is agarose.

29. The article of manufacture of claim 27 or 28, wherein the active agent is a peptide or protein.

30. The article of manufacture of any one of claims 27 to 29 in combination with written labeling instructions for administration of the particles by transdermal or transmucosal, high-velocity, powder injection.

31. A method for delivering a drug to a subject in need thereof, which method comprises

- preparing a pharmaceutical composition of any one of claims 21 to 24,
- accelerating said particles to a high velocity, and
- delivering said accelerated particles into a target skin or mucosal site.

32. The process of claim 31, wherein the hydrogel is agarose.

33. The process of claim 31 or 32, wherein the active agent is a peptide.

34. A process for making a powdered pharmaceutical composition, which process comprises:

- providing a mixture of pre-formed hydrogel particles having a size range of about 10 to 100 μm,
- suspending the particles in an aqueous composition having dissolved therein a pharmacologically active agent for a period sufficient to cause the particles to swell and incorporate the active agent therein, and
- removing water and other solvents from the suspension to form solid hydrogel particles having the active agent incorporated therewith and each particle having a diameter about 10 to 100 μm.

35. The process of claim 34, wherein the hydrogel particles are added to the aqueous composition while in a dry state.

36. The process of claim 34, wherein the hydrogel particles are added to the aqueous composition while in a wet, pre-swollen state.

37. A process for making a powdered pharmaceutical composition, which process comprises:

(a) forming an aqueous pharmaceutical formulation

comprising a pharmacologically-active agent and a hydrogel, the hydrogel being present at about 0.1 to 10 wt % of the formulation; and

(b) drying the formulation to obtain particles having an mean mass aerodynamic diameter of 10 to 100μm.

38. A powder which is suitable for delivery to a subject by particle injection and which comprises a hydrogel loaded with a pharmacologically active agent, for use in a method of treatment of the human or animal body by therapy.